Problem of Amputations in Patients with Newly Diagnosed Diabetes Mellitus

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A reduction of 50 % or more in diabetes-related amputations is a primary target of the St Vincent Declaration. This is thought to be achievable because both primary and secondary preventative healthcare strategies are effective in reducing the incidence of diabetic foot ulceration and progression to amputation. Unfortunately there is a group who cannot benefit from preventative health care, that is, newly diagnosed diabetic patients with already established severe complications. Using our population-based district diabetes information system we investigated, during the period 1 January 1992 to 31 December 96, the incidence and prevalence of lower extremity amputations (LEAs) and the proportion occurring in patients newly or recently diagnosed as having diabetes. Seventy-nine diabetic patients (59 male, 20 female) were recorded as having had 94 LEAs, the incidence of diabetes-related LEA being 475 per 100 000 diabetic patient-years. Of these LEAs 16 (20.2 %) were performed within 1 year of diabetes being diagnosed. This study highlights an appreciable and previously unrecognized problem: patients presenting with established complications of diabetes who cannot benefit from secondary preventative healthcare. These patients pose a potential obstacle to achieving targets for reductions in diabetes-related amputations.

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Introduction

Patients with diabetes have a very high risk (15–60 times greater than that of the non-diabetic population) of non-traumatic lower extremity amputations (LEAs). This is due to the complications of peripheral arterial disease and peripheral sensorimotor neuropathy.[1,2] Nevertheless, there are data showing that many LEAs can be prevented[3,4] and targets for reduction have been set accordingly. The St Vincent Declaration required a 50 % reduction in LEAs over a 5-year period.[5] Some patients however may be inaccessible to preventative healthcare because diabetes is not diagnosed until just before or even at the time of the LEA. Clearly this might mitigate the potential for reducing amputations through effective preventative care. Using our population-based district diabetes information system we have investigated, during a 4-year period, the incidence and prevalence of LEA and the proportion occurring in people newly or recently diagnosed as having diabetes.

Patients and Methods

Salford is a healthcare district in Greater Manchester, UK. Its population is 230 510, with approximately 50 % having a Jarman index >30, implying moderate/severe deprivation.[6] The Office of Population Censuses and Surveys (OPCS) mid-year population estimates for 1995 give the age and sex distribution of the Salford population is shown in Table 1. The Salford District Diabetes Information System (SDDIS) was established in 1992 and is used by all local primary care and hospital diabetes services. We examined data on LEA from SDDIS between the dates 1 January 1992 and 31 December 1996. Information recorded on SDDIS is based upon the UK Diabetes dataset[7] and is updated and verified during annual structured, preventative care review. Routinely, major adverse outcome data, such as LEA, are validated annually by linking the details recorded on SDDIS with treatment episodes coded on local hospital information systems and the records of the regional limb fitting centre, to which all major amputees are referred (OPCS tabular list of the classification of surgical operations and procedures fourth revision, ICD 9 and ICD 10).[8] Briefly, patients are uniquely identified using surname, forename, date of birth, and, where possible, postcode. These are compared with similar data in hospital discharge records and for matching patients diagnosis, procedure and discharge codes (primary and secondary)

Abbreviations: LEA lower extremity amputation, SDDIS Salford District Diabetes Information System, DM diabetes mellitus, JI Jarman Index, TI Townsend Index

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Table 1. The age/sex distribution of people in Salford district (1995). The corresponding distribution is given for the diabetic population (number of people with Type 1 DM)

Age (years)	Diabetic population			District population		
	Total (Type 1 DM)	Male (%)	Female (%)	Total	Male (%)	Female (%)
<45	747 (469)	431 (9)	316 (6)	143 863	74 740 (32)	69 123 (30)
45–64	1886 (240)	1080 (22)	806 (16)	49 324	24 811 (11)	24 513 (11)
65–74	1324 (85)	689 (14)	635 (13)	20 457	9 152 (4)	11 305 (5)
>75	984 (43)	364 (7)	620 (13)	16 866	5 418 (2)	11 448 (5)
Total	4941 (837)	2564	2377	230 510	114 121	116 389

are extracted automatically. These data are then re-coded to correspond to the relevant diabetes register data fields (e.g. OPCS (surgical procedures) code X095* translates to the 'below knee amputation' field), compared to the SDDIS dataset and discrepancies identified. For some datafields (e.g. myocardial infarction) the process is automated. For amputation, however, the numbers are very small. OPCS does not specify the site of amputation so the operation notes are retrieved and checked where discrepancies arise. Finally, to ensure best possible precision of ascertainment for this study, the case records of all amputees identified by SDDIS were examined and checks carried out to ensure that there were no discrepancies between SDDIS and the hospital podiatry records.

Lower extremity amputation (LEA), as defined by the LEA study group,[9] is the surgical removal of any part of the lower limb: a major LEA being defined as an amputation through or proximal to the ankle joint; a minor LEA as distal to the ankle joint. Because individual patients may have more than one LEA, the number of LEAs exceeds the number of amputees. Type 1 (insulin-dependent) diabetes mellitus (DM) was defined as insulin treatment started within the first year of diabetes; others were termed Type 2 (non-insulin-dependent) diabetes. An amputation was classed as potentially inaccessible to preventative care if it occurred within the first year of diagnosed diabetes.

For all subjects identified as having undergone a LEA, and all patients registered with SDDIS, the most recent demographic and social data with the metabolic and diabetes-related data from the same year the patient had their LEA were obtained from SDDIS. LEA subject characteristics (total, within first year, after first year, major LEA and minor LEA) and the remaining patients without LEA (non-LEA) are shown in Table 2. The Townsend and Jarman scores, calculated from the postcode, were used as a measure of socioeconomic deprivation.[6,10] The Jarman Index (JI) uses indicators of material as well as social deprivation, each weighted according to its likely effect on primary care workload, whereas the Townsend Index (TI) uses only markers of material deprivation. Increasing scores indicate increasing deprivation.

The total number of lower extremity amputations within the district (April 1992 to March 1996), identified by OPCS surgical codes X07 to X11, were obtained from Salford and Trafford Health Authority using the regional central patients admissions database.

All laboratory analyses were performed by the biochemistry department of Hope Hospital Salford. HbA_{1c} was determined by enzyme immunoassay of whole blood (DAKO Diagnostics Ltd) (reference range 3.3–4.9 %). Serum cholesterol was measured on non-fasting samples by enzymatic colorimetric method on a Roche Integra analyser.

Statistical Analysis

Statistical evaluation was performed using the statistical software SPSS for Windows (SPSS Inc., Chicago, USA). Data are presented as mean ± SD. Between group comparisons were made using Yates corrected chi squared tests or unpaired *t*-testing as appropriate.

Results

In 1995 there were 4941 living patients registered with SDDIS representing 2.1 % of the local population; 837 (16.9 %) had Type 1 DM and 4104 (83.1 %) had Type 2 DM; 2564 (51.9 %) were male and 2377 (48.1 %) female. The distribution of Type 1 DM, Type 2 DM and the total population, by age and sex, is shown in Table 1. During the study period, 79 diabetic patients (59 male, 20 female) were recorded as having had 94 LEAs; 69 had had 1; 7 had had 2; 1 had had 3 and 2 had had 4 amputations. There were 32 major and 62 minor amputations (52 toe, 10 foot). Of the 10 subjects having multiple amputations, 5 underwent a major amputation preceded by a minor amputation, the others being amputations alone.

The characteristics of the LEA patients compared with the other patients are shown in Table 2 and the relationship to duration of diabetes in Figure 1. Sixteen (20.2 %) of all LEAs were performed within the first year of diagnosed diabetes. Ten (12.7 %) of the patients were diagnosed as having diabetes at the time of amputation. Mean age at amputation was 67 (range 27–90) years for females and 60 (range 35–79) years for males ($p<0.001$). At the time of amputation, 9 patients (11.4 %) were

Table 2. Demographic, metabolic, and risk factors associated with LEA for those non-LEA patients; patients undergoing LEA within the first year of diabetes being diagnosed, after the first year of diagnosis, and patients undergoing minor or major LEA. Data are presented as mean (SD)

Characteristics	Total register non-LEA	All LEAs	LEA 1st year	LEA >1st year	Major LEA	Minor LEA
Male/female	2561/2412	59/20[c]	10/6	49/14[c]	22/6[b]	37/14[b]
Type 1 DM/Type 2 DM	837/4101	17/62	2/14	15/48	9/19	8/43
(%)	16.9/83.1	21.5/78.5	12.5/87.5	23.8/76.2	32.1/67.9	15.7/82.3
Age 1st LEA (yr) (SD)		62 (12)	59 (14)	63 (12)	62 (12)	62 (13)
BMI	28.4 (5.5)	29.9 (5.8)	30.1 (7.1)	29.7 (5.6)	30.2 (6.5)	29.8 (5.7)
Smoking (%) yes/no	46/54	62/38	65/35[a]	62/38	50/50	69/31[b]
Jarman Index	19.3 (0.3)	21.1 (18.6)	22.5 (16.7)	22.9 (17.3)	19.1 (23.0)	22.2 (16.0)
Townsend Index	4.2 (0.1)	4.6 (3.7)	3.1 (4.7)	4.9 (3.4)	4.9 (4.2)	4.8 (3.3)
PVD (%)	10.8	65.8[c]	62.5[c]	62.7[c]	78.6[c]	72.5[c]
Neuropathy (%)	19.5	70.9[c]	75.0[c]	69.8[c]	67.9[c]	60.8[c]
Ischaemic ulcer (%)	2.8	59.0[c]	50.0[c]	61.9[c]	78.6[c,d]	49.0[c]
Neuropathic ulcer (%)	3.4	59.0[c]	62.5[c]	58.7[c]	57.1[c]	58.8[c]
No PVD, ulcers on neuropathy (%)	74.3	12.7[c]	12.5[c]	12.7[c]	14.3[c]	11.8[c]
Systolic BP (mmHg)	147 (23)	153 (28)	157 (29)	152 (28)	150 (29)	154 (28)
Diastolic BP (mmHg)	81 (15)	83 (11)	87 (13)	81 (11)	85 (6)	82 (12)
Glycated haemoglobin	6.2 (2.1)	6.5 (2.1)	5.8 (1.8)	6.8 (2.1)	6.5 (1.6)	6.5 (2.2)
Cholesterol	5.8 (2.0)	5.7 (1.4)	6.1 (1.2)	5.6 (1.4)	5.8 (1.5)	5.7 (1.3)

[a]$p<0.05$; [b]$p0.01$; [c]$p<0.001$ Total Register vs. individual group; [d]$p<0.01$ Major LEA vs Minor LEA.

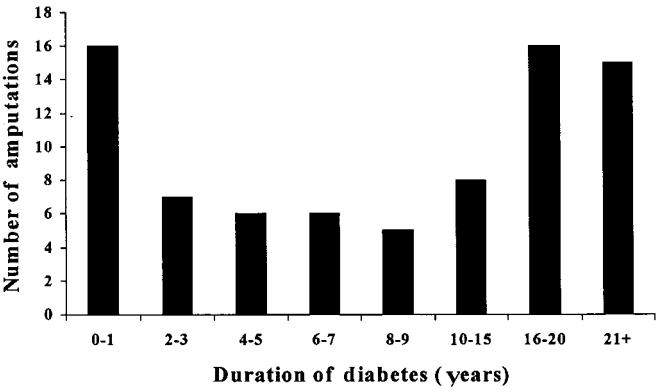

Figure 1. Number of diabetic patients undergoing amputation according to known duration of diabetes

managed by diet alone, 35 (44.3 %) with oral hypoglycaemic agents and 35 (44.3 %) were on insulin therapy (17 Type 1 DM, 18 Type 2 DM). In the year preceding LEA, 52 (70.9 %) subjects had a record of peripheral vascular disease (claudication, absent foot pulses, ischaemic pain or ischaemic ulceration), and 52 (65.8 %) of sensory neuropathy (sensory deficits, absent reflexes, painful neuropathy or neuropathic ulcer). Forty-seven subjects (59.5 %) had a prior history of neuropathic ulcers and 47 (59.5 %) of ischaemic ulcers. In 10 patients (12.7 %), preceding peripheral vascular disease or neuropathy was not recorded on the DIS. Casenote review confirmed that this was a true absence (rather than a recording failure) in 7 (88 %) out of 8 examined. Most patients undergoing a major LEA had preceding ischaemic ulceration. Patients undergoing minor LEAs or a LEA within the first year of diagnosis were significantly more likely to smoke compared to non-LEA patients (chi squared test $p<0.01$ for both).

Our data give an incidence of diabetes-related LEA of 10.2 per 100 000 population per year and 475 per 100 000 diabetic patient-years. If those subjects undergoing an amputation within the first year are excluded, the incidence of diabetes-related LEA was 394 per 100 000 diabetic patient-years. Thirty-three (75 %) of the diabetic amputees were male and 11 (25 %) female (chi squared $p<0.001$ compared to the district diabetic population). In a corresponding 4-year period, (1 April 1992 and 31 March 1996) 269 LEAs were performed in the non-diabetic population giving an incidence of 38.9 per 100 000 per year. The age-standardized incidence rate of diabetes-related LEAs was therefore 13.1 (95 % CI 9.0, 17.2) times greater than for the general population.

Discussion

In this population-based study 20.2 % of all patients undergoing diabetes-related amputation did so within a year of diabetes being diagnosed. These people cannot benefit from the structured preventative diabetes care which is proven to reduce the incidence of LEAs.[3,11] To achieve the goal of a 50 % reduction in diabetes-related amputations, proposed in the St Vincent declaration requires a 63 % reduction in diabetes-related amputations in the known diabetic population: a far more demanding target.

Few studies have reported the impact of this group of newly diagnosed patients, who present with established complications but presumably with a long history of undetected diabetes. Our results are, however, similar to those of Deerochanawong *et al.*[12] who reported that 15 % of LEAs were performed in patients in whom diabetes was diagnosed at the time of their amputation. They observed a mean duration of diabetes (range) of 7

(0–27) years for minor amputations and 5 (0–25) years for major amputations. Unfortunately most authors only provide a mean duration of diabetes prior to amputation and a typically large standard deviation suggesting a wide distribution, In contrast, Nelson *et al*,[13] in their study of Pima Indians, demonstrated a strong correlation between duration of diabetes and the incidence of the first LEA. Since all their patients had been screened bi-annually for diabetes, their true duration of diabetes is known and it is not surprising that few people presented with established complications. If patients undergoing LEA within the first year are excluded, our data also demonstrate a relationship between known duration of diabetes and the incidence of LEA.[14,15] A substantial reduction in complications is potentially achievable through screening of populations at high risk of developing Type 2 DM.

Most studies, including our own, show that the incidence of diabetes-related LEA is greater in men than in women (four times in this study). This has been attributed to higher rates of smoking in men.[16] We found no difference in smoking habits between men and women or between those undergoing a LEA within the first year or later. Smoking was more frequent among patients undergoing a major LEA or a LEA within the first year compared to the non-LEA diabetic population. The usual risk factors of PVD and neuropathy were prevalent in LEA patients and ischaemia was the most common reason for major amputations. No significant differences in social deprivation, glycaemia (as assessed by glycated haemoglobin), cholesterol or blood pressure were observed at the time of LEA between the index patients and non-LEA patients.

The recent incidence and prevalence of LEA within Salford district is comparable to the lower rates in the highly variable previously published data (Table 3). Many factors may underlie the discordant rates, including the prevalence of diabetes, the completeness of ascertainment of either diabetes itself or of LEA, the definition of LEA, and the local provision of podiatry and vascular surgery. Some studies have included only people undergoing their first LEA,[17–19], whereas others also include people who have already had a LEA;[12,18] some only include major amputations (above or below knee)[18] whereas others also include minor amputations.[12,19] Problems of comparison are further compounded by the different methods used to identify LEAs, ranging from hospital discharge data through surgical operation records and records from regional limb appliance centres to data from the state health statistics department.[12,20,21]

The incidence of LEAs, expressed as the rate per 100 000 per year in a diabetic population, is sensitive to the accuracy with which the background prevalence of diabetes is known. In our district, 2.1 % of the population are registered as having diabetes, and this prevalence has remained steady since 1992. The local population is mainly Caucasian (96 %), so that the high prevalence rate, which is higher than in many previous UK studies[22,23] cannot be explained by racial factors. Our prevalence, however, is similar to that observed in the recent DARTS study,[24] which used a different means of estimating the prevalence of diabetes in a Caucasian population, and it is likely that the completeness of our diabetes information system, hospital discharge data, surgical procedure codes, district podiatry records and the regional limb fitting centre data make our assessment particularly accurate.

The Salford incidence and prevalence of diabetes-related LEAs are at the lower end of previous estimates[12,19] (Table 3) but are still 10 times greater than in the non-diabetic population. The prevalence of foot ulceration however remains high and is comparable to other published series (Table 4). Foot ulceration, as confirmed in this study, is one of the strongest predictors of LEA.[25,26] This suggests that it has been improved secondary preventative foot care for high risk patients, e.g. early referral, increased and more effective use of podiatry, more sophisticated vascular surgery, and more timely preventative amputations[3] which accounts for our historically lower major LEA rates. Some major amputations

Table 3. Summary of studies which have measured the incidence of LEA in the diabetic population

Reference	Population studied	Study period	Rate 100 000^{-1} year^{-1} in diabetic population
This study	Salford, UK	1992–96	450
Deerochanawong[12]	Newcastle upon Tyne, UK	1989–91	570
Farrell *et al* (1993)[26]	Cherokee Indians, USA	1982–89	1210
Rith-Najarian *et al* (1993)[27]	Chippewa Indians, USA	1986–88	1600
Moss *et al*. (1992)[28]	Wisconsin, USA	1980–86	550
Nelson *et al*. (1988)[13]	Pima Indians, USA	1972–84	1370
Lee *et al*. (1993)[14]	Oklahoma Indians, USA	1972–80	1800
Lawee and Csima (1992)[29]	Ontario, Canada	1987–88	444
Valway *et al* (1993)[30]	Indian Health service	1982–87	1712 (Tuscon) 1364 (Phoenix) 651 (Oklahoma) 535 (Navajo)
Waugh (1988)[2]	Tayside, UK	1980–82	1010

Table 4. The prevalence of major amputations and diabetic foot ulcers in the Salford and Oxford districts

Age (years)	Major amputation (%)		Foot ulcers (%)	
	Oxford 1987	Salford 1996	Oxford 1987	Salford 1996
<50	1	0.50	2	2.8
50–70	3	1.8	6	11.1
>70	4	0.55	8	6.1

are, sadly, still unavoidable and are largely due to irremediable distal peripheral vascular disease (78 % of major amputations in our series). Nonetheless further progress may be possible through improved primary prevention of ulceration. However, it remains the case that patients presenting with concurrent diagnosis of diabetes and advanced foot disease cannot benefit from any of these strategies. This study highlights an appreciable, and previously unrecognized, problem: patients presenting with established complications of diabetes who cannot benefit from secondary preventative healthcare. Perhaps screening for diabetes in asymptomatic, high-risk patients may also be a necessary strategy to minimize diabetes-related complications.

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